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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,997	02/05/2004	Kjell Malmlof	5904.214-US	5384

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EXAMINER	
AUDET, MAURY A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,997	MALMLOF ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/05/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.0-a

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 5-9, and 11-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Knudsen et al. (US 2002/0011071 A1, now issued as US 6,458,924 B2).

Knudsen et al. teach the use of growth hormone (claim 223) and GLP-1 (claim 163), for suppressing appetite, reducing weight, and treating obesity or diabetes (¶'s 0012, 0071, 1633, 1635, 1650; claims 112, 118, 218, 228, and 230), by subcutaneous injection (¶'s 1637, 1746; claim 231), in a composition with a carrier (¶'s 1603, 1634, 1842; claim 229).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knudsen et al. (US 2002/0011071 A1, now issued as US 6,458,924 B2).

Knudsen et al. is discussed above. The reference discuss that the dosage range of the compositions administered therein are dependent upon the type of diet which the patient/mammal is on (see Gao et al., col. 29, lines 60-65; and Knudsen et al., ¶'s 1636, 1649). However, the reference expressly teaches administration of the compositions to a patient/mammal on a "low fat diet" (Applicant's claims 4 and 10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the present compositions directed to suppressing appetite to a patient/mammal on a low fat diet in Knudsen, because the reference expressly teach that the administration dosage is dependent upon the diet which the patient/mammal is on, and one of skill in the art applying this appetite suppressing composition/method to patient's/mammal's suffering from obesity and/or diabetes would be motivated to administer the aforementioned to a

patient/mammal on a low fat diet because an obese or diabetic patient/mammal is routinely directed medically to be on a low fat diet.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gao et al. (US 6191160) in view of Knudsen et al. (US 2002/0011071 A1, now issued as US 6,458,924 B2).

Gao et al. teach the use of growth hormone secretagogues (col. 27, line 26) and GLP-1 (col. 27, line 34) for appetite suppression (i.e.. "inhibit obsessive food intake and the resulting obesity and complications associated therewith"; (col. 1, lines 27-30)), for the treatment of obesity/diabetes (col. 27, lines 10-15 and 22-34; claim 15; abstract), by subcutaneous injection (col. 27, lines 51-58), in a composition with a carrier (col. 27, lines 51-57; claim 15). Although Gao et al. teach the use of growth hormone secretagogues, known to increase growth hormone secretion, Gao et al. does not expressly teach the use of growth hormone singly (which inherently has the same systematic effect as secretagogues).

Gao et al. also discuss that the dosage range of the compositions administered therein are dependent upon the type of diet which the patient/mammal is on (see Gao et al., col. 29, lines 60-65). However, the reference does not expressly teaches administration of the compositions to a patient/mammal on a "low fat diet" (Applicant's claims 4 and 10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer a growth hormone, in place of growth hormone secretagogue, in the methods of Gao et al., because Knudsen et al. advantageously teach the use of human growth hormone for the same methods. One of skill in the art would be motivated to combine the

teachings of Gao et al. and Knudsen et al, because both teach the same method of treating appetite suppression using the same underlying biochemical pathway through growth hormone and the substitution of human growth hormone for a growth hormone secretagogue is well within the judious selection of one of ordinary skill in the art.

Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the present compositions directed to suppressing appetite to a patient/mammal on a low fat diet in Gao et al., because the reference expressly teach that the administration dosage is dependent upon the diet which the patient/mammal is on, and one of skill in the art applying this appetite suppressing composition/method to patient's/mammal's suffering from obesity and/or diabetes would be motivated to administer the aforementioned to a patient/mammal on a low fat diet because an obese or diabetic patient/mammal is routinely directed medically to be on a low fat diet.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 17 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, and 18 of U.S. Patent No. 6,458,924 B2 (''924", Common Assignee). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '924 patent teach the use of GLP-1 in a composition with an antiobesity agent (e.g. growth hormone, col. 155, lines 33-40 "antiobesity agent"). Although the claims do not expressly claim that the composition is formulated for injection, this is readily obvious since the specification describe the compositions may be formulated for injection (col. 157, lines 13-25). [It is noted that although the claims are drawn to compositions of GH with GLP-1, the claims are not drawn to methods of using GH with GLP-1, for appetite suppression].

Claim Rejections - 35 USC § 112 1st Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of *treating* impaired appetite regulation, does not reasonably

provide enablement for *preventing* impaired appetite regulation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention: The claimed invention is drawn to a method of treating (and preventing) impaired appetite regulation.

The state of the prior art and the predictability or lack thereof in the art:

Murphy (US 3,856,942) teach that obesity (or impaired appetite regulation) is not preventable by pharmacologic invention (col. 10, lines 6-20):

The patients on this weight maintenance program were quite similar in their histories. Prior to joining the clinical trial, they had been on and off diets for years, often under treatment with pharmacologic agents. None reported that they could maintain their weight loss, even though it was considerable in some cases, for any protracted period after reducing to their desired weight. All blamed their failures on traditional dieting methods, i.e., diets that prohibited eating and drinking most of the foods and beverages they desired or reducing by means of pharmacologic agents. Consequently, in the past, once their goal had been achieved, the impulse was to revert to indulging in foods and beverages, which their tastes demanded, in unrestricted amounts. They had not been adequately conditioned to do otherwise. Thorn and Bondy, (Obesity, in Principles of Internal Medicine, edited by Harrison TR, Adams, Bennett et al, 5th ed. New York, McGraw-Hill Book Co., 1966, p 398) in evaluating the pharmacological treatment of obesity also have found that as soon as the pharmacologic effect wears off, or the medication is discontinued, appetite will return, and weight gain will recur, unless the patient' s inherent capacity to control his food intake has been altered fundamentally.

The amount of direction or guidance present and the presence or absence of working examples:

Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). Applicants have reasonably demonstrated/ disclosed that the claimed growth hormone composition is useful as a therapeutic agent for treating appetite diseases or disorders and/or reducing the risk thereof (see entire document). However, the specification does not provide any evidence (studies/experiments or otherwise) that

the present invention is capable of preventing impaired appetite regulation.

The breadth of the claims and the quantity of experimentation needed:

The claims also encompass using the claimed compounds to *prevent* impaired appetite regulation, which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does the term "treat", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) - including preventing such disorders as impaired appetite regulation (which clearly is not recognized in the medical art as being a totally preventable condition).

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the claimed methods which would function to *prevent* impaired appetite regulation.

It is suggested that the claims be amended to be limited in scope to methods of *treating* impaired appetite regulation.

Claim Rejections - 35 USC § 112 2nd ¶

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is unclear what is contemplated by the phrase "appetite suppression". The phrase "appetite suppression" or "suppressing appetite" or "appetite-suppressive" in e.g. claims 1, 14, and 17 is a relative term which renders the claim indefinite. The similar phrases are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Specification page 2, lines 34-35 describes suppressing appetite, specifically in obese animals, but does not indicate for what duration or what is contemplated by this or related phrases. As claimed, appetite suppression could encompass complete satiety or merely minutes to hours of satiety.

Claim 1 recites the limitation "mammal" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the term "mammal" be deleted and "patient" inserted.

In claim 8, it is unclear what "disease[s] or disorder[s]" are contemplated as being associated with "impaired appetite regulation", to which the invention may treat. Impaired appetite regulation could encompass all appetite diseases, from those associated with individuals who cannot eat or do not eat enough (bulimia, anorexia), to those who eat too much (obesity). Specification (page 2, line 7) appears to only contemplate use of the invention to treat obesity (since the other diseases identified in the specification are listed as indirectly caused by obesity, the underlying disease/disorder). Furthermore, e.g., claims 1, 14, and 17 are drawn to use of the invention to suppress appetite, indicating use for those who eat too much. Therefore, it is unclear what is contemplated by "impaired appetite regulation".

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, 06/20/2004

Bruce Campell

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